IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: WAVE 4 CASES	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF PAUL J. MICHAELS, M.D.

Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in support of their motion to exclude the testimony of Dr. Paul J. Michaels.[1]

Prior to this litigation, Dr. Michaels had examined approximately 24 mesh explants over a seven or eight year period. Ex. B, Michaels 6/18/16 Dep. 12:19–13:1. He has no specific training regarding polypropylene mesh—much less the Prolene mesh at issue. *Id.* at 14:18–15:2. He has never authored any papers, conducted any research, or lectured on the impact of polypropylene mesh on tissue in the pelvic floor. *Id.* at 15:3–14. Indeed, Dr. Michaels admits that prior to his work in this litigation:

- he knew nothing about the degradation of polypropylene mesh in the body, other than his general belief that polypropylene sutures could degrade, and had no knowledge of Prolene sutures or mesh degrading *in vivo* (*id.* at 52:4–53:8);
- he never analyzed polypropylene to determine the extent to which it may have degraded *in vivo* (*id.* at 54:3–7);
- he never studied the mechanisms of degradation of any polypropylene material in the body (*id.* at 55:7–56:9); and
- he had not studied the alleged correlation between inflammation and pain, which he concedes is "extremely complex and not something that I, as a pathologist generally would report or describe" (*id.* at 98:11–24).

[1] This motion applies to those cases identified in Ex. A. Ethicon requests a hearing pursuant to Federal Rules of Evidence 104(a) and 104(c) to demonstrate that Dr. Michaels's testimony is inadmissible.

Despite a lack of knowledge pertaining to pelvic mesh, generally, or Ethicon mesh products, Dr. Michaels seeks to offer general causation opinions in this litigation, including:

- Ethicon mesh products degrade, become brittle, and lose their mechanical properties *in vivo*, causing complications including an increased inflammatory response and scarring;
- Ethicon mesh products contract, shrink, and deform *in vivo*, resulting in complications like erosions, scarring, and chronic pain;
- Ethicon's internal documents and testimony by Ethicon employees demonstrates that they Ethicon was aware of the alleged flaws in Ethicon mesh products, including its alleged propensity to degrade, contract, and cause complications.

Dr. Michaels has done no testing of any type to support these opinions which were formed solely for litigation. He simply read some articles provided by Plaintiffs' counsel and reviewed prior expert reports of Dr. Vladimir Iakovlev. S*ee id.* at 68:18–69:10; 73:21–74:2. Dr. Michaels reviewed materials pertaining to Dr. Iakovlev's opinions "since he's a pathologist expert in this litigation as well [and] I wanted to see the types of questions that he was being asked." *Id.* at 72:19–73:1. Although Dr. Michaels claims that he also conducted independent research, he cannot identify those authorities or distinguish them from those Plaintiffs provided. *Id.* at 19:2–8.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1–3 (S.D. W. Va. July 8, 2014).

I. The Court Should Exclude Dr. Michaels's Degradation Opinions.

Dr. Michaels contends that the body's inflammatory response to mesh triggers an oxidative burst of free radicals and peroxides that degrade the surface of mesh fibers *in vivo*. Ex. C, Michaels Rep. at 3–4. He claims that the degraded mesh becomes brittle, cracks, and loses strength. *See id.*; *see also* Ex. B, Michaels 6/18/16 Dep. 63:2–9. He further opines that this degradation causes increased inflammation, scarring, and other complications. *See id.*; *see also id.* at 60:5–10.

A. Dr. Michaels's opinion that Prolene degrades *in vivo* is unreliable.

1. Dr. Michaels's general experience as a pathologist is not an adequate basis for his degradation opinions.

Dr. Michaels bases his opinion that Ethicon mesh products degrade *in vivo* on his general pathology experience. Yet he has no specialized knowledge necessary to offer that expert testimony. *See* Fed. R. Evid. 702.

Dr. Michaels's pre-litigation knowledge of degradation was limited to a belief that sutures composed of generic polypropylene could degrade *in vivo*. Ex. B, Michaels 6/18/16 Dep. 52:4–19 (admitting that he did not recall reading anything about the alleged degradation of pelvic mesh prior to his retention). Dr. Michaels admits that this knowledge was not based on any scientifically validated methodology, but rather observations from a single abdominal surgery and a general "discussion in the past" about suture materials. *See id.* at 54:8–55:6; *see also id.* at 55:12–56:9.

Further, Dr. Michaels conceded that even this limited understanding did not extend to sutures composed of Prolene—the material from which Ethicon mesh products are made. *Id.* at 52:20–53:8.[2] It cannot be said that offering an opinion based on products different those at issue—here, Prolene—is consistent with the "intellectual rigor" employed by pathologists outside the courtroom. *See Marsh v. W.R. Grace & Co.*, 80 F. App'x 883, 886 (4th Cir. 2003).

2. Dr. Michaels's degradation opinions are not the product of reliable testing.

a. Testing is a key factor in determining the reliability of expert opinion.

In *Nease,* the Fourth Circuit reaffirmed the importance of testing to assess the reliability of an expert's opinion. The plaintiff in *Nease* alleged that he crashed a truck because of "mechanical binding" of its speed-control cable. 848 F.3d at 221-23. The plaintiff's expert opined that the

[2] This Court previously questioned whether Prolene is distinct from other forms of polypropylene. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014). However, even Plaintiffs' experts admit Prolene is different from generic polypropylene due to its proprietary antioxidants. *See, e.g.*, Ex. D, *Huskey* 8/25/2014 Trial 156:14–18; 157:11–17 (Dr. Scott Guelcher, plaintiff's biomaterials scientist, concedes Prolene's antioxidant package differentiates is from generic polypropylene); *see also* Ex. E, Guelcher 3/23/16 Dep. 87:23–88:9 (same).

speed-control assembly in plaintiff's truck permitted contaminants to bind the speed-control cable, which resulted in the accident. *Id.* at 231. The court explained that, while *Daubert* is a "flexible test" in which no one factor is dispositive, "[o]ne especially important factor for guiding a court in its reliability determination is whether a given theory has been tested." *Id.* at 231. An untested theory may be plausible and "may even be right[,] . . . [but] it is no more than a hypothesis, and thus is not knowledge, nor is it based upon sufficient facts or data or the the product of reliable principles and methods applied reliably to the facts of the case." *Id.* (citation omitted).

The Fourth Circuit reversed because the expert "never tested [the truck] to determine whether it is actually possible for enough debris to accumulate" such that binding could occur, and "conceded that he never ran any tests to confirm his theory." *Id.* The expert's "failure to test his hypothesis renders his opinions on the cause of [the] accident unreliable." *Id.* The court further explained that while "scientific methodology involves generating hypotheses and testing them to see if they can be falsified," the expert merely "presented a hypothesis only [and] failed to validate it with testing." *Id.*[3] Applying the teachings of *Nease* to Dr. Michaels's degradation opinions, it is clear that the Court should exclude these opinions as unreliable for the same reasons.

b. Dr. Michaels did not conduct the testing required to establish degradation, embrittlement, or lost mechanical properties.

As Plaintiffs' polymer scientists concede, it is necessary to conduct tests, including Fourier transform infrared spectroscopy, scanning electron microscopy ("SEM"), gel permeation chromatography, and tensile strength testing, to determine whether a polymer has degraded. *See* Ex. F, Mays 3/2/16 Dep. 47:16–49:7 (identifying tests that can assess degradation); Ex. G, Jordi

[3] The remaining *Daubert* factors supported exclusion of the expert's opinion because (i) he failed to publish or otherwise subject his theory to peer review; (ii) his poor "methodology" rendered it impossible to determine a rate of error; and (iii) a company document identifying potential failure modes did not constitute "general acceptance" of the expert's theory. *Id.* at 232-33.

10/30/13 Dep. 173:25–174:8 (admitting that test results showing no loss of molecular weight suggests no degradation of polypropylene).

Dr. Michaels did not run any of the tests required to detect degradation. *See* Ex. H, Michaels *Carter* 6/18/16 Dep. 60:8–20 (did not conduct SEM, transmission electron microscopy ("TEM"), or analytical chemistry); Ex. I, Michaels *Chrysler* 6/18/16 Dep. 55:6–17 (did not conduct SEM, TEM, or mechanical testing). Nor did he identify any reliable studies establishing that Prolene degrades, becomes brittle, or loses mechanical properties *in vivo*. *See infra* at § I.B. Thus, the Court should exclude Dr. Michaels's degradation opinions as "unsupported by any evidence such as test data or relevant literature in the field." *See Nease*, 848 F.3d at 234.

c. Dr. Michaels's subjective analysis is insufficient to establish that Prolene becomes embrittled or loses mechanical properties.

Despite failing to run the tests required to determine whether Prolene loses mechanical properties, Dr. Michaels attempts to rely on his gross examination of about "two dozen" mesh explants not at issue in this litigation. In fact, Dr. Michaels admitted that his embrittlement opinion is based solely on his "examination of the gross specimens in the past[.]" Ex. B, Michaels 6/18/16 Dep. 64:14–65:10 (conceding that he "didn't examine any of the[] specimens [in this litigation] grossly."). Similarly, he seeks to base his opinion that Ethicon mesh products lose mechanical properties on how mesh "felt" after explantation in comparison to his memory of how other mesh "fe[lt] like and function[ed] like before" implantation. *Id.* at 66:17–67:8. But Dr. Michaels's analysis lacks a control or standards of any kind, rendering his subjective opinions inconsistent with the scientific method.

Dr. Michaels opinions regarding embrittlement have no scientific basis. He did not conduct any testing using objective criteria or subject to a known failure rate, submit his findings to peer-review, or follow a generally accepted methodology. *See, e.g.,* Ex. B, Michaels 6/18/16 Dep. 65:6–7 (explaining that he did not "biochemically" analyze the gross mesh specimens). Significantly,

Dr. Michaels could not identify any specific mechanical property that Ethicon mesh products supposedly lose due to degradation. *Id.* at 65:20–66:11.

Instead, Dr. Michaels's opinions are based solely on his subjective assessment as to how certain mesh explants "felt" versus his recollection of how other mesh "felt" before implantation. *See id.* at 64:14–19; 66:17–67:8. But Dr. Michaels conceded that he has not "felt" Ethicon mesh products in many years, and he has never "felt" others. Ex. H, Michaels *Carter* 6/18/16 Dep. 37:20–38:6 (testifying that he had not held TVT since medical school, and he could not recall ever holding Prolift). Thus, even where Dr. Michaels had previously "felt" a pristine version of the mesh, his gross examination was many years removed from that time.

Furthermore, Dr. Michaels admitted that "half" of the two dozen meshes he grossly examined had previously been treated with formalin. Ex. B, Michaels 6/18/16 Dep. 41:16–42:1. In other words, half of the explants on which Dr. Michaels bases his opinions that Ethicon mesh products become embrittled and lose mechanical properties had been subjected to a chemical used to stiffen and fix specimens as a part of the sample preparation process.

Finally, Dr. Michaels has not produced any of the non-litigation pathology samples, or the pathology reports pertaining to those samples. *Id.* at 65:11–19. And while he claims that "most" of the meshes he grossly examined were Prolene meshes, this is speculative and based on his memory of operative reports. *See id.* at 67:9–68:5 (admitting that he "didn't do a particular count" of the meshes). These opinions constitute the same sort of unreliable and irrelevant testimony that this Court has repeatedly excluded. *See, e.g.,* Ex. J, *Lewis v. Ethicon*, 2:12-cv-04301, MDL No. 2327, 2/12/14 Trial 18:19–19:3; *Lewis v. Ethicon*, No. 2:12-cv-4301, MDL 2327, 2014 WL 186872 (S.D. W. Va. Jan. 15, 2014).

Dr. Michaels's subjective and speculative opinions simply do not satisfy the requirements of *Daubert*. *See Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999). Accordingly, the Court should preclude him from offering his opinions at trial.

d. Dr. Michaels's methodology is unreliable.

In Wave 2 cases, Dr. Michaels claimed that he could observe a layer of degraded Prolene, which he refers to as "bark," using polarized light microscopy. This opinion was omitted from his Wave 4 report. Thus, Dr. Michaels cannot offer a "bark" opinion in Wave 4. *See* Fed. R. Civ. P. 26(a)(2)(B)(i) (requiring an expert report to include "a complete statement of all opinions the witness will express and the basis and reasons for them."); *Bethune v. Boston Sci. Corp.*, No. 2:13-CV-06199, 2016 WL 2983697, at *5 (S.D. W. Va. May 20, 2016) (holding testimony using sources or opinions that were undisclosed in the expert report were excluded on Rule 26 grounds); *Fowler v. Boston Sci. Corp.*, No. 2:13-CV-03932, 2016 WL 3162122, at *5 (S.D. W. Va. June 3, 2016) (same); *In re Ethicon, Inc.,* No. 2:12-CV-4301, 2014 WL 186872, at *17 (S.D. W. Va. Jan. 15, 2014) (excluding expert's opinions that were not present in report).

The Court should preclude Dr. Michaels from offering these opinions because they are unreliable. Dr. Michaels based his approach on the work of Dr. Iakovlev and an internal Ethicon document. *See, e.g.,* Ex. H, Michaels *Carter* 6/18/16 Dep. 62:2–8. But neither of these sources are a reliable basis for Dr. Michaels's use of polarized light to determine whether Ethicon's meshes degrade. And to the extent Dr. Michaels bases his opinions on Dr. Iakovlev's work, his opinions are unreliable for the same reasons discussed in Ethicon's motion to exclude Dr. Iakovlev's opinions and testimony. *See* Mot. to Exclude the Opinions and Testimony of Dr. Vladimir Iakovlev & Mem. in Supp., *In re Ethicon, Inc.*, MDL 2327, No. 2:12-cv-01267 [ECF #2070].

Dr. Michaels's reliance on a 32-year old internal Ethicon test is equally unfounded, because that test is subject to the same flaw as Dr. Iakovlev's methodology. The Ethicon researchers also

failed to use a control to validate the underlying hypothesis that degraded Prolene would hold stain. *See* Ex. K, ETH.MESH.15955462. Dr. Steven MacLean—an expert for Ethicon—has performed this experiment and proven that degraded Prolene cannot hold stain. *See* Ex. L, Expert Report of Dr. Steven MacLean, at 53-71; *see also* Ex. M, S. Benight, *et al.*, *Microscopy of Intentionally Oxidized Polypropylene-Based Mesh Material*, Soc'y of Plastics Engineers (May 2016).

No scientifically valid testing supports Dr. Michaels's opinion. For this reason, and because the scientific literature on which he relies does not support his opinions, the Court should preclude Dr. Michaels from offering these opinions at trial. *See Nease*, 848 F.3d at 234.

3. The scientific literature on which Dr. Michaels relies does not support his degradation opinions.

Dr. Michaels bases his degradation opinions on articles and internal Ethicon documents. Ex. C, Michaels Rep. at 6–7. He admits that he never saw these materials prior to his work for Plaintiffs, Ex. B, Michaels 6/18/16 Dep. at 57:9–24, and concedes he cannot identify any articles that he found through independent research, *id.* at 19:2–8. More importantly, these articles do not stand for the proposition that Prolene implanted in the pelvic floor degrades.

a. Dr. Michaels relies on articles that do not address Prolene.

Not Prolene and Speculative. Dr. Michaels seeks to base his degradation opinions on an article by Costello. Ex. C, Michaels Rep. at 6; *see also* Ex. N, C.R. Costello, *et al.*, *Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient*, 14 Surg. Innov. 168 (2007). The Costello paper analyzed three different hernia mesh explants: (i) Gore-Tex; (ii) a heavyweight polypropylene mesh manufactured by Bard; and (iii) Proceed, an Ethicon Prolene mesh coated with oxidized cellulose. Ex. N, Costello, at 169–70. Although the Bard mesh degraded, there was no such evidence for the Ethicon mesh. *Id.* at 172–75. In fact, the authors found that the Ethicon "specimen did not possess *any* visible surface

degradation." *Id.* at 175 (emphasis added). Indeed, all of the article's findings about the degradation of polypropylene are actually limited to the Bard mesh.

Cannot Confirm Either Oxidation or Prolene. Dr. Michaels relies on a 2010 article by Clave to support his opinion that Prolene degrades. *See* Ex. C, Michaels Rep. at 6–7; *see also* Ex. O, A. Clave, *et al.*, *Polypropylene As A Reinforcement In Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants*, 21 Int. Urogynecol. J. 261 (2010). But the Clave paper, encompassing 100 meshes from multiple manufacturers, expressly states that while there are many "hypotheses concerning the degradation of the PP . . . [n]one of these, particularly direct oxidation, could be confirmed in this study." *Id.* at 266.

Not Prolene and Not Pelvic Mesh. Dr. Michaels also relies on an article by Wood. *See* Ex. C, Michaels Rep. at 6; *see also* Ex. P, A.J. Wood, *et al.*, *Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient*, 24 J. Mater. Sci. Mater. Med. 1113 (2013). But the Wood article did not analyze Prolene. Furthermore, the article expressly states that it only analyzed hernia meshes.

b. Dr. Michaels' reliance articles are irrelevant and unsound.

Exposure to Conditions Not Found in the Pelvic Floor. Dr. Michaels seeks to rely on an article by Jongebloed as evidence that Prolene degrades after implantation. *See* Ex. C, Michaels Rep. at 5; *see also* Ex. Q, W. Jongebloed & J. Worst, *Degradation of Polypropylene in the Human Eye: A SEM Study*, 64 Documenta Opthamologica 143 (1986). But this article is inapposite because it addressed sutures that had been implanted in the human eye. It is undisputed that all forms of polypropylene, including Prolene, oxidize when exposed to ultraviolet radiation. Thus, the fact that ocular sutures, which are exposed to ultraviolet radiation, oxidize after implantation in the eye is neither surprising nor germane to the Prolene used in the female pelvic floor.

Unreliable Methodology. Dr. Michaels points to an article by Mary to support his opinion that Prolene undergoes oxidative degradation. Ex. C, Michaels Rep. at 6–7; Ex. R, C. Mary, *et al.*, *Comparison of the* In Vivo *Behavior of Polyvinylidene Flouride and Polypropylene Sutures Used in Vascular Surgery*, 44 Am. Soc'y Articial Internal Organs J. 199 (1998). The Mary article's authors did not conduct molecular weight analysis or test the mechanical properties of the sutures. Rather, they concluded Prolene sutures had oxidized based on FTIR test results showing a peak at 1,740^{cm-}, which "has been assigned to carbonyl stretching, and identifies the presence of surface oxidation, because the chemical structure of both pure polymers are devoid of this functional group." *Id.* at 201. But the authors failed to recognize that 1,740^{cm-} is also the wavelength for one of the antioxidants used in Prolene, a fact conceded by Plaintiffs' materials scientists. *See, e.g.*, Ex. F, Mays 3/2/16 Dep. 104:24–105:3 (admitting that one of the antioxidants used in Prolene has an FTIR signature of 1,740^{cm-}). Thus, the article failed to confirm that the peak at 1,740^{cm-} was oxidation, rather than a reading of the antioxidant package used in Prolene.

In addition, the sample preparation process used in the Mary article introduced error into the SEM results. Specifically, the article explains that after explantation, the sutures designated for SEM analysis were treated with either formalin or gluteraldehyde prior to cleaning. Ex. R, Mary at 200. The authors ignored the fact that both formalin and gluteraldehyde crosslink with the proteinaceous layer on the fibers to form a hardened shell that can manifest as a cracked layer under SEM. *See* Ex. S, Expert Report of Shelby Thames, at 10, 16–21 (explaining that fixatives used in sample preparation, such as formalin, bond or crosslink with proteins adhered to the surface of an explant to form a hard and brittle shell around the surface of the explant).

Antioxidants Work. Dr. Michaels relies on a 1976 article by Liebert to support his opinions that polypropylene is subject to oxidative degradation. *See* Ex. C, Michaels Rep. at 6; *see also* Ex. T, T. Liebert, *et al.*, *Subcutaneous Implants of PP Filaments*, 10 J. Biomed. Mater. Res.

939 (1976). But, as even other experts for Plaintiffs in this MDL have admitted, Liebert actually found that antioxidants are effective in preventing degradation in polypropylene. *See* Ex. U, Guelcher 3/25/14 Dep. 73:16–74:1.

c. Dr. Michaels relies on unpublished Ethicon documents regarding Prolene sutures that do not support his opinion.

Dr. Michaels also relies on internal Ethicon documents, including, a 1987 Prolene suture test. Ex. C, Michaels Rep. at 6–7, *see also* Ex. V, IR Microscopy of Explanted Prolene (Sept. 30, 1987), ETH.MESH.13334286. However, this test found no change in molecular weight which Plaintiffs' experts concede is required to prove degradation. *See* Ex. G, Jordi 10/30/13 Dep. 173:25–174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene). Nor did the test make any findings that the sutures' mechanical properties—such as elongation and tensile strength—diminished.

Dr. Michaels also relies on a 1983 Prolene suture test. Ex. C, Michaels Rep. at 6; *see also* Ex. W, B. Matlaga Ltr. to Dr. A. Lunn (Mar. 23, 1983), ETH.MESH.15955438–73. Yet, as Plaintiffs' polymer chemist admitted at deposition, the 1983 suture test only examined one fiber explant. Ex. F, Mays 3/2/16 Dep. 99:9–100:8. He also could not rule out the possibility that the fiber analyzed in the test was damaged during excision. *Id.* at 100:23–101:4.

Because Dr. Michaels's opinions are unsupported by reliable testing or relevant scientific literature, the Court should exclude his opinions as unreliable. *See Nease*, 848 F.3d at 234.

B. Dr. Michaels's opinion that degradation causes complications is unreliable.

Dr. Michaels opines that degradation causes increased inflammatory response and scarring that correlate with unspecified clinical symptoms. Ex. B, Michaels 6/18/16 Dep. 58:11–59:7; 59:19–60:13. Dr. Michaels fails to identify any testing or scientific literature that supports the proposition that the degradation of Prolene in Ethicon mesh products causes clinical complications.

See Nease, 848 F.3d at 234 (explaining that opinion "unsupported by any evidence such as test data or relevant literature in the field" should be excluded).

Although Dr. Michaels claims that his opinions regarding the complications allegedly caused by degradation are based on scientific literature, he was unable to identify any such studies. *Id.* at 60:14–20; *see also id.* at 106:6–14 (testifying that he could not remember any studies supporting his opinions regarding clinical complications). And while he pointed to certain studies regarding degradation in his expert report, *see* Ex. C, Michaels Rep. at 6, examination of those studies reveals that they do not actually support his opinion that the alleged degradation of Prolene causes clinical complications, *see supra* at § I.A.3..

Furthermore, Dr. Michaels's opinion that degradation causes clinical complications fails to account for the out-of-court writings of Dr. Iakovlev, who acknowledges that the question remains open. *See, e.g.,* Ex. X, V. Iakovlev, *et al.*, *Pathology of Explanted Transvaginal Meshes* 512 (2014) ("Polypropylene degradation *may play a role* in the continuous inflammatory response, mesh hardening, and late deformations" and the "chemical products of degradation *need to be studied* for their composition and effect on the tissue.") (emphasis added); Ex. Y, V. Iakovlev, *et al.*, *Degradation of Polypropylene* In Vivo: *A Microscopic Analysis of Meshes Explanted From Patients*, J. Biomed. Mater. Res. Part B (2015) ("[The] exact mechanisms of these late complications are yet to be understood").

The Court should preclude Dr. Michaels from testifying about complications allegedly caused by degradation because his opinions are not based in scientific evidence.

II. Dr. Michaels's Opinions Regarding the Alleged Contraction, Shrinkage, and Deformation of Ethicon Mesh Products Are Unreliable.

Dr. Michaels seeks to testify that Ethicon mesh products contract, shrink, or deform *in vivo*. *See* Ex. C, Michaels Rep. at 2–5; Ex. B, Michaels 6/18/16 Dep. 39:21–40:5. He claims that such

contraction leads to clinical complications, like erosion, scarring, and chronic pain. Ex. C, Michaels Rep. at 2–5. But Dr. Michaels fails to identify any reliable support for his opinions.

Dr. Michaels's contention that he can look at a pathology slide and infer that mesh contracted or deformed *in vivo* is unfounded. Dr. Michaels failed to follow the standard methodology used by pathologists for determining how a specimen is oriented in the human body.[4] Ex. Z, William Westra, *et al.*, Surgical Pathology Dissection (2003), at 4; Ex. AA, Susan Lester, Manual of Surgical Pathology (2010), at 7. Rather, he simply concluded that a specimen that had a folded appearance during his examination was also folded *in vivo*.

But as Dr. Maria Abadi—one of Ethicon's expert pathologists—explained, "if [a mesh] comes [out] folded, it has nothing to do with the way it was positioned *in vivo*," because the explanting surgeon subjects the explant to a variety of forces during the removal. *See* Ex. BB, Abadi 3/31/16 Dep. 99:19–101:9 (without information from the surgeon, orientation of a specimen is "all speculation"). Here, Dr. Michaels failed to consider the forces applied to mesh during excision, as he made no effort to understand the removal process. *See* Ex. B, Michaels 6/18/16 Dep. 46:22–47:6. Further, Dr. Michaels admits that the tissues into which Ethicon mesh products are implanted contracts immediately upon excision. *Id.* at 42:14–43:17. Nor did he account for the contraction caused by formalin fixation during the sample preparation process.

Dr. Michaels employed the same "methods" as Dr. Iakovlev, which the Court excluded in Wave 1, noting that Plaintiffs did not bother to dispute the lack of reliability of those methods. *See*

[4] To ascertain how a specimen was oriented *in vivo*, a pathologist must (i) identify anatomical landmarks, and (ii) consult markers provided by the explanting surgeon. Ex. Z, Westra, at 4; Ex.AA, Lester, at 7. Specifically, the surgeon must use sutures, tags, or a diagram to designate the orientation (*i.e.,* anterior, posterior, medial, lateral, superior, and inferior positioning) of the specimen. *See* Ex. Z, Westra, at 4; Ex. AA, Lester, at 7. The failure to adhere to this methodology at the time of explantation eliminates the pathologist's ability to determine the *in vivo* orientation of the specimen, and renders conclusions as to its *in vivo* appearance speculative. *See* Ex. Z, Westra, at 4; Ex.AA, Lester, at 7.

Mem. Op. and Order (*Daubert* Motion re: Vladimir Iakovlev), at 8 (S.D. W. Va. Sept. 1, 2016) [ECF # 2710] ("Wave 1 Iakovlev Order").

Dr. Michaels's opinions regarding mesh contracture or deformation are nothing but speculation and should be excluded. *See Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork").

III. Dr. Michaels's Opinions Regarding Complications Are Unreliable.

A. Dr. Michaels's analysis is unreliable because he failed to use a control.

Dr. Michaels's opinions that Ethicon mesh products cause complications are based on his histological analysis of explanted meshes. Dr. Michaels's opinions are inconsistent with the scientific method because he failed to offer compare his histological observations to asymptomatic comparator. *See* Ex. CC, Expert Report of Teri Longacre at 5; Ex. DD, McLendon Report at ¶ 6; Ex. EE, Vogel Report at 14. Dr. Michaels's failure to use a control means that he cannot eliminate the likelihood that the histological presentation of women suffering from pain is the same as the histology of women not suffering from pain. *See* Vogel Report at 14.

This is a significant flaw in Dr. Michaels's analysis because if the histology of both groups is the same, the histological findings do not identify the cause of the pain. The same holds true as to all of the complications to which he opines. Without a proper control, Dr. Michaels's attempted correlation of specific complications to histological features is nothing but conjecture. *See Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *28 (S.D. W. Va. Oct. 17, 2014) ("Vigorous adherence to protocols and controls are the hallmarks of 'good science.'").

Dr. Michaels's methods are essentially identical to those used by Dr. Iakovlev, whose opinions regarding complications have been excluded by this Court. *See* Wave 1 Iakovlev Order at 8-9. The same result should obtain here.

B. Dr. Michaels's opinion that Ethicon mesh products cause inflammation that results in pain is unreliable.

Dr. Michaels opines that Ethicon's mesh causes pain due to inflammation. *See, e.g.*, Ex. C, Michaels Rep. at 3–4. But Dr. Michaels admitted that "mechanism with regards to inflammation and pain is . . . not something that I, as a pathologist generally would report or describe." Ex. B, Michaels 6/18/16 Dep. 98:11–17. And while he offered *theories* as to how inflammation could cause pain, *see id.* at 99:1–100:5, he admitted that was "not something that I have specifically reviewed in preparation" of his opinions, *id.* at 98:23–24. Nor did Dr. Michaels identify any medical literature to support his opinion that the presence of inflammation permits the causal conclusion that a patient suffered from pain. *Id.* at 106:6–14. In fact, the only study that Dr. Michaels could recall—the Hill study—contradicts his hypothesis that higher levels of inflammation correlate with higher levels of pain.

The Hill study examined 130 explanted meshes and compared the inflammation levels of patients who complained of pain and those who did not. Ex. FF, A. Hill, *et al.*, *Histopathology of Excised Midurethral Sling Mesh*, 26 Int'l Urogyncology J. 591, 592 (2015). Contrary to their hypothesis, the authors found pain was *not* associated with increased inflammation. *Id.* at 592–93.

Dr. Michaels seeks to avoid the results of the Hill study by claiming that it was "a really bad study." Ex. B, Michaels 6/18/16 Dep. 102:13–106:5. He criticizes Hill's reliance on medical records and speculates that patients who had pain did not report it. This critique makes no sense: retrospective studies based on medical records are commonplace and Dr. Michaels has not identified any scientific literature to the contrary.

Dr. Michaels's rejection of the findings of the Hill study is significant because it conducted the analysis that Dr. Michaels has not done—*i.e.*, using a control and comparing the histological reaction of symptomatic and asymptomatic meshes. Dr. Michaels's failure to conduct such an analysis renders his opinions unreliable. Assuming *arguendo* that Dr. Michaels's criticisms of the

Hill study have merit, it was the only study he could identify. Ex. B, Michaels 6/18/16 Dep. at 106:6–14. Thus, in the absence of Hill, his opinions are unsupported by scientific literature.

C. Dr. Michaels's opinion that the presence of a nerve in scar tissue or its proximity to mesh is indicative of pain is unreliable.

In Wave 2, Dr. Michaels sought to opine that the presence of a nerve in scar tissue or its proximity to mesh fibers are sufficient to conclude that a patient experienced pain. *See* Ex. GG, Michaels *Sierra* Report at 6 & 11 (fig. 11). No similar opinions were disclosed in his Wave 4 report. To the extent Dr. Michaels seeks to offer such opinions in Wave 4, the Court should exclude them on this basis alone. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *Bethune*, 2016 WL 2983697, at *5; *Fowler*, 2016 WL 3162122, at *5; *In re Ethicon*, 2014 WL 186872, at *17.

The Court should also exclude these opinions as unreliable. Dr. Michaels failed to identify any scientific literature supporting this opinion. Moreover, the Hill study found no difference in fibrosis between symptomatic and asymptomatic patients. *See* Ex. FF, Hill at 593.

Dr. Michaels also misunderstands the basic structure and function of nerves. As Drs. Hannes Vogel and Roger McLendon—Ethicon's neuropathologists—explain, only sensory nerve fibers are capable of transmitting pain signals. *See* Ex. DD, Expert Report of Roger McLendon ("McLendon Report") at 9 (explaining function of motor, autonomic, and sensory nerves); Ex. EE, Expert Report of Hannes Vogel ("Vogel Report") at 3–6 (same). Thus, one cannot link a specific nerve to pain without first determining that it is, in fact, a sensory nerve. And even if it is a sensory nerve fiber, one must identify the sensory receptor to ascertain the type of signal the nerve carries. *Id.* at 6; *see also id.* at 4 (explaining that sensory nerves carry different types of signals); Ex. DD, McLendon Report at 9 (same). One cannot draw a conclusion regarding pain without identifying a sensory receptor, because the receptors—not the nerve fiber itself—trigger the transmission of a pain signal. *Id.*; *see also id.* at ¶ 14.

The histological stains used by Dr. Michaels, H&E and S100, do not permit a pathologist to draw a conclusion about the cause of pain. *See* Ex. GG, Michaels *Sierra* Report at 5 & 11 (fig. 11). It is impossible to distinguish sensory, motor, and autonomic nerves by reviewing a slide stained with H&E. Ex. B, Michaels 6/18/16 Dep. 78:21-79:10. Indeed, even neuropathologists cannot differentiate between nerve types via light microscopy. *See* Ex. CC, Vogel Report at 6.

In addition, although stains like S100 help identify certain nerve components, they cannot distinguish between nerve types and "do not identify sensory receptors." *Id*. Moreover, while Dr. Michaels observed that there are stains capable of differentiating nerves, he does not use such stains or conduct any such analysis in this litigation. Ex. B, Michaels 6/18/16 Dep. 79:11-16.

Dr. Michaels's lack of familiarity with neuropathology demonstrates a lack of specialized knowledge regarding the subjects about which he seeks to testify and contributes to his failure to apply a scientifically legitimate methodology for concluding that Ethicon mesh products cause pain in women.

IV. The Court Should Exclude Dr. Michaels's Alternative-Design Opinions.

In his report, Dr. Michaels discussed alternative mesh designs that allegedly do not present the same risks as Ethicon mesh products, including absorbable mesh materials and meshes incorporating larger pores. Ex. C, Michaels Rep. at 2-3. But his discussion of alternative designs is unsupported by testing or scientific literature demonstrating that his proposed alternatives are actually safer than—and at least as effective as—Ethicon mesh products.

A. Expert opinions regarding alternative designs must be supported by testing or scientific literature demonstrating that the proposed alternative is actually safer.

As the Fourth Circuit recently explained in *Nease,* an expert's alternative-design opinion must be excluded under *Daubert* if the expert failed to establish that the alternative design is actually safer using reliable testing or scientific literature. 848 F.3d at 219. The plaintiff in *Nease* crashed a truck he was driving because he was unable to stop, allegedly due to the "mechanical

binding" of the truck's speed-control cable. *Id.* at 221-23. The plaintiff's expert proposed three alternative designs to the speed-control cable which purportedly would have prevented the accident. *Id.* at 234. The court noted that the expert based his opinions on the fact that the manufacturer had used "all of these alternative design features [in other vehicles] for many years by the time the [truck] was produced." *Id.*

The Fourth Circuit held the expert's alternative design opinions were unreliable because they were unsupported by testing or scientific literature. *Id.* The court had previously explained that while *Daubert* is a "flexible test" and no single factor is dispositive, "[o]ne especially important factor for guiding a court in its reliability determination is whether a given theory has been tested." *Id.* at 231. In the absence of supportive testing or scientific literature, an expert's theory may be plausible and "may even be right[,] . . . [but] it is no more than a hypothesis, and thus is not knowledge, nor is it based upon sufficient facts or data or the the product of reliable principles and methods applied reliably to the facts of the case." *Id.* (citation omitted).

Applying these principles, the court found that the expert "performed no tests or studies to determine whether, in fact, these older, long-standing designs were involved in fewer binding incidents." *Id.* at 234. The expert similarly "offered no data from any other studies or accident records to prove that the older designs were less likely to bind than the one incorporated" in the truck. *Id.* Rather, the expert "simply proclaimed without any support that the alternative designs he identified were safer than the design of the speed control cable assembly in the [truck]." *Id.*

For these reasons, the court concluded that the "testimony should have been excluded as it was 'unsupported by any evidence such as test data or relevant literature in the field.'" *Id.* (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999)). Importantly, the court explained that the "fact that the [proposed] alternatives have generally been in use for decades is wholly insufficient to prove that such designs were safer" in the context of the accident at issue, or "that

reasonably prudent manufacturers would have adopted them." *Id.* In applying the teachings of *Nease* to Dr. Michaels's opinions, it is clear that the Court should preclude him from testifying about potential alternative designs for the same reasons.

B. Dr. Michaels's alternative design opinions are unreliable.

Dr. Michaels has no reliable basis to testify that absorbable materials or larger pore mesh would have been safer and feasible to treat SUI or POP. *See* Ex. C, Michaels Rep. at 2-3. Dr. Michaels has not conducted any testing on absorbable materials or larger pore mesh. Nor did he identify even a single clinical study to prove the safety and efficacy of a device used to treat SUI or POP composed of the alternate materials.

Dr. Michaels acknowledged at deposition that he had not "discuss[ed] any use of a material that should have been used in contrast to what was used" in Ethicon mesh products, or even "reviewed material with respect to th[e] subject." Ex. B, Michaels 6/18/16 Dep. 96:19-97:8. Similarly, he admitted that he had no opinion as to the size a pore needs to be to reduce the risks allegedly associated with Ethicon mesh products. *Id.* at 35:24-36:9. Ultimately, he conceded that he would not "tell a surgeon, for this particular patient you need to use this material; for that patient you should use that material." *Id.* at 93:17-94:21.

This Court should preclude Dr. Michaels from offering opinions regarding alternative designs because he failed to support these with testing and peer-reviewed studies required under F. R. Evi. 702 and *Daubert*. *See Nease*, 848 F.3d at 234; *Oglesby*, 190 F.3d at 249 (requiring test data or relevant literature showing testing by others); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 681–82 (S.D. W. Va. 2014) (flawed testing failed to meet peer-reviewed standards).

V. The Court Should Exclude Dr. Michaels's Narrative Summary of Ethicon Documents and Depositions, and His Opinions Concerning Ethicon's Knowledge, State of Mind, and Corporate Conduct.

Dr. Michaels also opines about Ethicon's alleged knowledge of certain issues. For instance, he opines that Dr. Klosterhalfen informed Ethicon in 2006 that "the foreign body reaction to these meshes can occur up to 20 years." *See* Ex. C, Michaels Rep. at 6. He argues that "Ethicon's documents demonstrate that over the course of Dr. Klosterhalfen's interactions and meetings with Ethicon, he made numerous suggestions aimed at improving the biocompatible nature of mesh implants[.]" *Id.* He also interprets and characterizes trial testimony by Ethicon personnel. *Id.* at 5.

The Court should preclude Dr. Michaels from offering opinions concerning Ethicon's internal documents, corporate knowledge, and conduct. This Court has repeatedly ruled that an expert's opinions regarding Ethicon's documents and corporate knowledge "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *See, e.g., Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *5 (S.D. W. Va. Jan. 15, 2014) (citation omitted). Although an expert can rely on corporate documents in certain instances in formulating his opinions, the material quoted above demonstrates that Dr. Michaels seeks to go well-beyond mere reliance by editorializing on Ethicon's alleged knowledge and conduct.

Dr. Michaels is a pathologist. His resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000). Dr. Michaels is thus unqualified to offer any opinions concerning Ethicon's corporate conduct.

Respectfully submitted,

/s/ *David B. Thomas*
David B. Thomas (W. Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street, Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1807
dthomas@tcspllc.com

/s/ *Christy D. Jones*
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway,
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
Christy.jones@butlersnow.com

COUNSEL FOR DEFENDANTS ETHICON, INC., ETHICON LLC, AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on April 13, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *David B. Thomas*
David B. Thomas (W. Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1807
dthomas@tcspllc.com